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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,108	04/08/2004	Frank A. Morello	UTXC:768US	8228
32425	7590	05/03/2007		
FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			EXAMINER NGUYEN, HUONG Q	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 05/03/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/821,108	<b>Applicant(s)</b> MORELLO, FRANK A.	
	<b>Examiner</b> Helen Nguyen	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/24/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 3736

## DETAILED ACTION

### *Priority*

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged, namely, priority to provisional application #60461495, filed on 4/9/2003.

### *Information Disclosure Statement*

2. The information disclosure statement (IDS) submitted on 6/24/2004 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### *Claim Objections*

3. **Claim 11** is objected to because of the following informalities: "by" should be "be." Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-2 and 7-12** are rejected under 35 U.S.C. 102(b) as being anticipated by Lobodzinski et al (US Pat No. 5078688).

Art Unit: 3736

6. In regards to **Claim 1**, Lobodzinski et al disclose a medical device comprising: an outer needle having a shaft (32), a passageway, an open end communicating with the passageway, and side openings (36) in the shaft that communicate with the passageway; and a stylet (24) having a tapered distal end and a stylet shaft configured to be slidably positioned within the passageway of the outer needle, best seen in Figures 1-3 and 7, the stylet shaft having different cross-sectional areas at different locations along the stylet shaft due to the beveled point, best seen in Figures 11a-b.

7. In regards to **Claim 2**, Lobodzinski et al disclose the distal end of the stylet (24) comprises a sharp tip (28) that fits closely against a portion of the inner surface of the passageway.

8. In regards to **Claim 7**, Lobodzinski et al disclose the outer needle (32) includes a hub (41) (Col.3: 44-46).

9. In regards to **Claim 8**, Lobodzinski et al disclose the hub includes a notch (Col.3: 44-46).

10. In regards to **Claim 9**, Lobodzinski et al disclose the stylet (24) includes a hub (26).

11. In regards to **Claim 10**, Lobodzinski et al disclose the hub of the stylet includes a male portion configured to mate with the notch in the hub of the outer needle, best seen in Figure 1.

12. In regards to **Claim 11**, Lobodzinski et al disclose the outer needle (32) is configured to attach to a valve (31) that includes an opening that allows the stylet (24) to be slidably positioned

Art Unit: 3736

within the passageway of the outer needle when the valve is attached to the outer needle, best seen in Figure 1.

13. In regards to **Claim 12**, Lobodzinski et al disclose the outer needle (32) is configured to allow a lung biopsy needle to be slidably inserted into the passageway.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. **Claims 3-6 and 25-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobodzinski et al in view of Linder (US Pat No. 5643230)

16. In regard to **Claims 3-6 and 25-28**, Lobodzinski et al disclose the invention recited but do not disclose the specific arrangement of the side openings. Linder teaches an analogous device with analogous side openings spaced at least 1 cm apart, where the side openings located farthest from each other are at least 2-7 cm apart (Col.1: 25-32). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lobodzinski et al such that two side openings are spaced greater than 1 cm apart and the side openings located farthest from each other are at least 2-7 cm apart, as taught by Linder, to provide the most appropriate configuration of the side holes for the desired device use.

17. In regards to **Claim 29**, Lobodzinski et al disclose the outer needle (32) includes a hub (41).
18. In regards to **Claim 30**, Lobodzinski et al disclose the hub includes a notch.
19. In regards to **Claim 31**, Lobodzinski et al disclose the stylet (24) includes a hub (26).
20. In regards to **Claim 32**, Lobodzinski et al disclose the hub of the stylet (24) includes a male portion configured to mate with the notch in the hub of the outer needle (32), best seen in Figure 1.
21. In regards to **Claim 33**, Lobodzinski et al disclose the outer needle (32) is configured to attach to a valve (31) that includes an opening that allows the stylet (24) to be slidably positioned within the passageway of the outer needle when the valve is attached to the outer needle, best seen in Figure 1.
22. In regards to **Claim 34**, Lobodzinski et al disclose the outer needle (32) is configured to allow a lung biopsy needle to be slidably inserted into the passageway.
23. In regards to **Claim 35**, Lobodzinski et al disclose a method of performing a medical procedure on a subject, the method comprising inserting the medical device into the subject (abst).
24. **Claims 13-14 and 19-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobodzinski et al in view of Saker et al (US Pat No. 6840952).

Art Unit: 3736

25. In regards to **Claim 13**, Lobodzinski et al disclose the invention recited but do not disclose said outer needle shaft having a 16-gauge to 19-gauge outer diameter. Saker et al disclose that analogous needle shafts designed for analogous medical procedures are advantageously designed with a 16-gauge to 19-gauge outer diameter (Col.1: 18-28). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lobodzinski et al such that said outer needle shaft has a 16-gauge to 19-gauge outer diameter, as taught by Saker et al, to advantageously provide an optimal size for the desired device use.

26. In regards to **Claim 14**, Lobodzinski et al disclose the distal end of the stylet (24) comprises a sharp tip (28) that fits closely against a portion of the inner surface of the passageway.

27. In regards to **Claim 19**, Lobodzinski et al disclose the outer needle (32) includes a hub (41).

28. In regards to **Claim 20**, Lobodzinski et al disclose the hub includes a notch.

29. In regards to **Claim 21**, Lobodzinski et al disclose the stylet (24) includes a hub (26).

30. In regards to **Claim 22**, Lobodzinski et al disclose the hub of the stylet (24) includes a male portion configured to mate with the notch in the hub of the outer needle (32), best seen in Figure 1.

Art Unit: 3736

31. In regards to **Claim 23**, Lobodzinski et al disclose the outer needle (32) is configured to attach to a valve (31) that includes an opening that allows the stylet (24) to be slidably positioned within the passageway of the outer needle when the valve is attached to the outer needle, best seen in Figure 1.

32. In regards to **Claim 24**, Lobodzinski et al disclose the outer needle (32) is configured to allow a lung biopsy needle to be slidably inserted into the passageway.

33. **Claims 15-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobodzinski et al in view of Saker et al, further in view of Linder.

34. Lobodzinski et al as modified by Saker et al in the manner above disclose the invention recited but do not disclose the specific arrangement of the side openings. Linder teaches an analogous device with analogous side openings spaced at least 1 cm apart, where the side openings located farthest from each other are at least 2-7 cm apart (Col.1: 25-32). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lobodzinski et al as modified by Saker et al such that two side openings are spaced greater than 1 cm apart and the side openings located farthest from each other are at least 2-7 cm apart as taught by Linder to provide the most appropriate configuration of the side holes for the desired device use.



Art Unit: 3736

35. **Claims 36-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobodzinski et al in view of Linder or Saker et al, further in view of Goldberg et al (US Pat No. 5356386).

36. Lobodzinski et al as modified by Linder or Saker et al in the manner above teach the invention claimed but do not teach the device for obtaining a lung biopsy by using an external source of suction and preventing pneumothorax. Goldberg et al teach an analogous device using an external source of suction to obtain a lung biopsy while preventing pneumothorax (Col.5: 65-68). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lobodzinski et al as modified by Linder or Saker et al to include an external source of suction for the application of taking a lung biopsy while preventing pneumothorax, as taught by Goldberg et al, as a useful application of the device for taking necessary lung biopsies while preventing the harmful effects of pneumothorax.


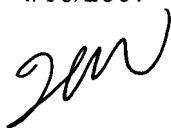
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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